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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,223	06/13/2001	Izumu Saito	Q63988	5950

7590

11/20/2002

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/20/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant(s)

09/807,223

Examiner

Myron G. Hill

Applicant(s)

SAITO ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1- 44 is/are pending in the application.
- 4a) Of the above claim(s) 13- 20, 43, and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,9. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Election was made **without** traverse in Paper No. 10, filed 27 August 2002 of Group I, claims 1- 12 and 21- 41. Claims 13- 20 and 43- 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1- 12 and 21- 41 are under consideration in this action.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: The claim ends in a comma but should end in a period. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5, 22, 28- 32, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear that the recited elements all constitute a promoter or if promoter is meant to be something other than what is normally known in the art. Splice acceptor sites and poly-A sites are not normally considered part of a promoter.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 12 and 21- 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy (WO 97/32481) and Wahl et al. (WO 92/15694).

Hardy teaches expression of Cre in 293 cells, a nuclear localization signal, human beta actin promoter, a poly A signal from beta actin. Hardy also teaches that there is the possibility that if Cre is expressed all the time, there could be a negative selective pressure towards what the Cre is acting on, that functionally expressed Cre is needed, and that functional Cre expressing cells can be made by many ways that are well known in the art (page 14, lines 6- 31, page 23, lines 11- 23, and Example 3 starting on page 31).

Hardy does not teach recombinase flp or the recombinase flp recognition site- frt.

Wahl teaches a site specific gene activation system (specific protein expression) using flp recombinase to control expression of a gene product in a manner that depends on expression of recombinase flp. This expression system uses a stuffer DNA (neomycin) which is flanked by frt sites and which suppresses the expression of the downstream gene, and excision of the neomycin by recombinase flp leads to expression of the downstream gene. When the cell containing this expression cassette has recombinase flp introduced into it, the nucleic acid sequences upstream of the gene of

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interest are removed by the specific action of the recombinase and the gene of interest is now expressed (page 4, lines 20- 28, page 22 line 18- page 23, line 25, and Figure 1B).

One of ordinary skill in the art would know that there are many enhancers, promoters, splice acceptor, and a poly A signals that function in 293 cells are known in the art and selection of the specific ones would be a matter of routine optimization. Cre expression could be controlled as taught by Wahl in the gain of function expression cassette that uses *frt* sites to direct excision of DNA when recombinase *flp* is added to get expression of the gene of interest, in this case Cre. Knowing that recombinase *flp* is needed to be expressed in the cells to obtain Cre expression, one of ordinary skill in the art would know that expression of an exogenous protein can be achieved by infection with a recombinant adenoviral expression vector that expresses recombinase *flp*.

Thus, it would be *prima facie* obvious to control the expression of Cre as taught by Hardy in the expression method of Wahl with the expectation of success.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
November 15, 2002

  
JAMES HOUSEL 11/18/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600